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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/337,675	06/22/1999	JON SWANSON	029318/0497	9275

31049 7590 08/01/2011

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
08/01/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	09/337,675	SWANSON ET AL.
	Examiner	Art Unit
	SUSAN TRAN	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-22,25-36,38-40,42-44,46-48 and 50-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-22,25-36,38-40,42-44,46-48 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.	6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03/04/11;05/23/11;06/10/11;07/08/11.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/08/11 has been entered.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4, 8-13, 30-36, 38-40, 46-48 and 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. WO 96/20698 A2.

This rejection has been withdrawn in view of Applicant's Amendment filed 06/10/11.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanson et al. US 2007/0048378 A1.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Swanson teaches a controlled release formulation comprising a rate controlling polymer, a nanoparticulate drug and at least one surface active agent associate with the surface of the drug (paragraphs 0039-0042). Drug includes drugs in crystalline phase (paragraph 0044). The claimed particle size is found in paragraph 0057. Suitable surface modifiers are found in paragraphs 0051-0054. Rate controlling polymer includes HPMC, polyethylene oxide, or polyvinyl acetate phthalate, which can be found in paragraph 0060. The composition has a controlled release rate of from about 2 to about 24 hours (paragraph 0039). The composition further comprises binder, lubricant, filler, and other pharmaceutically acceptable excipients (paragraphs 0063-0069). The formulation can be prepared as a solid dispersion such as in the form of a tablet for oral administration (paragraphs 0083-0096).

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. US 2007/0048378 A1, in view of Baichwal US 6,093,420.

Swanson is relied upon for the reasons stated above. Although Swanson teaches a solid dispersion in the form of a tablet, in the case that Applicant can

successfully argue Swanson does not teach a matrix form, Baichwal is relied upon for such teachings.

Baichwal teaches a sustained release dosage form comprising NSAID dispersed uniformly in a polymer matrix (column 5, lines 65 through column 6, lines 1-30; column 9; and claims 19-22).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nanoparticulate composition of Swanson in a matrix tablet dosage form taught by Baichwal. This is because Baichwal teaches a polymer matrix useful for the controlled release of an NSAID, because Baichwal teaches a suitable controlled release matrix that has a controlled release rate of about 2 to about 24 hours (see Table 10), and because Swanson teaches the desirability to incorporate drug such as an NSAID into a solid dispersion that has a similar release rate, namely from about 2 to about 24 hours.

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liversidge et al. US 5,552,160, Baichwal US 6,093,420.

Liversidge teaches a dispersible particle composition comprising nanoparticulate drug and a surface modifier adsorbed on the surface of the drug. See abstract; columns 3-4; and claims. Suitable surface modifiers are found in columns 3-4. Drugs include naproxen, indomethacin, and ibuprofen (claim 5). Drug in crystalline phase is

found in column 2, lines 45-50. Liversidge further teaches the particle has an average particle diameter of less than 400 nm (claim 2).

Liversidge does not expressly teach formulating the nanoparticulate composition into a controlled release dosage form.

Baichwal teaches a sustained release dosage form comprising NSAID dispersed uniformly in a sustained release carrier (column 5, lines 65 through column 6, lines 1-30; column 9; and claims 19-22).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nanoparticulate composition of Liversidge in a matrix tablet dosage form taught by Baichwal. This is because Baichwal teaches a polymer matrix useful for the controlled release of an NSAID, because Baichwal teaches that uniformly dispersing an NSAID in a polymer matrix is well known in the art, and because Liversidge teaches that the resulting nanoparticles can be prepared with pharmaceutically well-known carriers in the art (column 6, lines 62-67).

Response to Arguments

Applicant's arguments filed 06/10/11 have been fully considered but they are not persuasive.

Applicant argues that Levy does not teach a surface stabilizer associated with the surface of drug particles.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615